



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D. C. 20231

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In re application of:

Robert E. Fischell ✓

For: Implantable, Programmable
Medication Infusion System

Serial No.: 034155 ✓

Filed: April 27, 1979 ✓

LETTER

Hon. Commissioner of Patents and Trademarks
Washington, D.C.

Sir:

Pursuant to Applicant's continuing duty under Rule 56,
Applicant has previously submitted two letters (including
lists of patents and publications) which relate to the above-
identified invention. A lengthy list of articles (provided
with the second letter of July 16, 1979) was cited in a
limited distribution report as including articles "relevant
to drug infusion systems." To facilitate the Examiner's
review of these references, Applicant offers the following
discussion of the apparently more significant articles.
Copies of articles not previously provided are enclosed here-
in.

Irsigler et al and Pickup et al each disclose a portable
dosage-regulating apparatus having an electronic control box.
No implantation is suggested. Specific circuitry or means
for effecting safe operation are not set forth.

Fogt et al teaches a closed-loop infusion system for
detecting glucose level, determining by computer means the
amount of medication required based on that level, and
delivering medication. The "heart of the system" is the

glucose level analyzer which is not a claimed part of the present invention. The safety features, structure, patient-physician programming and communication, and open loop design of the present invention are clearly absent from this reference.

Thomas et al discloses an implantable insulin delivery pump. The advantages of a piezoelectric pump providing a train of pulses at "resonance" are discussed. Programming infusion, providing redundant safeguards, telemetry communication, and various claimed pump features are not detailed in the reference.

Blackshear (in Scientific American and other cited articles) discusses the Infusaid implantable pump (by Metal Bellows Company of Sharon, Massachusetts) which continuously provides drug to a patient. No mention of dosage limiting, programmability, leakage prevention, or electronics for control or safety purposes is made in the reference.

Kraegan et al teaches an artificial pancreas which employs computer means in conjunction with a peristaltic pump to infuse drugs. Also a "module" independent of the computer means is included therein to monitor the pulse repetition rate of the pump. What the module is and how it functions is not discussed. The peristaltic pump does not provide the safety and power advantages of the pump claimed in the present invention. Clemens et al also employs a peristaltic pump.

Marliss et al discloses an artificial pancreas wherein infusion rates were determined by glucose measurements. Continuous, not commanded, infusion is disclosed in response to various algorithms based on glucose levels.

Santiago (Diabetes, Volume 28, No. 1) is provided for its discussion of insulin delivery systems and its review of the

Metal Bellows and Thomas et al pump devices. Santiago states that (as of 1979) existing infusion pumps "do not provide a mechanism for varying the rates of infusion delivery." The programmable feature of the present invention addresses this deficiency.

The above-discussed references are believed to be the more relevant references cited. A copy of each publication discussed above or in the patent application (and not previously provided) is enclosed herein. Other references included in the previously submitted list are material as providing background, alternative approaches (such as closed-loop artificial pancreas cells), clinical experimentation and comments suggesting the possible applications for and significance of the present invention, and general medical considerations. Such references are not discussed and are not provided.

Applicant also wishes to again make clear that the references cited are not necessarily prior art. Some of the cited articles post-date the invention as well as the filing of the patent application relating to the present invention.

Respectfully submitted,



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